

**HARMONIZATION OF
TECHNICAL STANDARDS
IN THE
EUROPEAN COMMUNITY:
IMPLICATIONS FOR ONTARIO AND CANADA**



1990/91

**A REPORT PREPARED FOR THE
ONTARIO MINISTRY OF INDUSTRY, TRADE AND TECHNOLOGY**



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EXECUTIVE SUMMARY

Standards-related developments in the European Community (EC) are fluid and still evolving. There may be some slippage in the timetable for implementation, but the broad policy directions are set.

Given the EC's firm policy commitment to removing technical barriers to intra-Community trade, it is essential that Canadian business take steps now to assess opportunities and challenges and to develop appropriate strategies.

1. Importance of the EC's Standards Agenda

Technical standards have acted as a major barrier to trade between EC member states. Most EC countries have their own technical regulations which set health, safety and environmental quality requirements for goods sold in their national markets. In addition, there are differences in voluntary product standards between member states, and testing and certification procedures are often not recognized from one member state to another.

The European Community's measures to harmonize standards and technical regulations form a major part of its 1992 program to create a single market in the EC. Almost 30% of the 285 directives that comprise the 1992 legislative agenda deal directly with technical standards. It has been estimated that over the next few years, over 1000 new European standards will have to be written (most of them before the end of 1992) in order to satisfy the requirements of the single market directives.

In addition to removing technical barriers to trade, the EC's objectives on standards relate to opening up government procurement and promoting technological and industrial development.

The business community in the EC perceives technical barriers to trade as one of their most important obstacles to conducting business between member states. This perception is shared by small, medium and large firms alike. Consequently almost 60% of EC firms expect a major positive impact from the removal of technical barriers in the Community.

2. The Benefits for Canada

While the EC's standards agenda will pose both risks and benefits for Canadian firms, on balance it should result in significantly improved access to the huge EC market of 325 million people.

The principal benefits will result from the introduction of a more coherent and transparent system throughout the Community. Rather than having to navigate through twelve different systems (as is the case now), Canadian exporters and producers will face only one set of EC standards and one set of testing and certification requirements to access all of the Community market.

Common European standards will reduce research, production and distribution costs for Canadian exporters to the EC, as well as for Canadian producers located in the Community.

The benefits of a single set of standards are not confined to the twelve member states of the European Community. The 1992 standards program also involves the six EFTA countries. If, as is likely, Eastern European countries adopt West European standards, the benefits of the EC initiative could extend to include a European market of over 500 million people.

The development of European standards is an important component in opening up the government procurement market in the EC. The revised Community directives on public supplies and works, and the directive covering procurement by entities in the telecommunications, transportation, energy and water supply sectors, all require purchasing entities to specify European standards wherever they exist (subject to some limited exceptions).

As the table on the following page demonstrates, Canadian exporters in most of Canada's major export sectors to the EC should gain from harmonization of standards, testing and certification in the Community.

It is also likely that small and medium-sized Canadian exporters will benefit relatively more than larger firms, since they have traditionally lacked the resources to overcome multiple standards hurdles in the Community.

EC 1992 Standards Developments
Impact on Selected Major Canadian Export Sectors to the EC

Sector	Magnitude of Positive Impact	Magnitude of Negative Impact
Telecom Equipment	Strong	Small
Telecom Services	Medium	Small
Forest Products	Strong	Medium
Autos and Parts	Medium	Small
Machinery	Medium	Small
Environmental Equipment	Strong	Small
Electrical/Electronic	Medium	Medium
Aerospace	Small	Small
Processed Foods	Medium	Medium

Source: See Section 5 of main report

3. Major EC Legislative Reforms

3.1 The EC's "New Approach" to Harmonizing Standards

The original approach to technical harmonization in the EC involved attempts to get Community-wide legislative agreement on detailed technical regulations. However, this proved to be a difficult and slow process, and progress was very limited.

Consequently a "new approach" to the reduction of technical barriers has been adopted, the main elements of which are:

Harmonization of Essential Standards

The EC's new approach directives will normally only lay down "essential requirements" for health, safety and environmental protection which must apply throughout the Community. These essential requirements can be met either through an independent test or by meeting a relevant standard. A list of new approach and other relevant directives is set out in Appendix D.

Development of European Standards

The task of writing detailed European standards which satisfy the "essential requirements" has been given to the European standards-setting bodies, such as CEN (the Committee for European Standardization), CENELEC (the Committee for Electrotechnical Standardization) and ETSI (the European Telecommunications Standards Institute). It is important to note that EFTA countries are members of these standards bodies; the US and Canada are not.

The European Commission, concerned with the slow pace of standards writing by CEN, CENELEC and ETSI, has recently released a Green Paper which sets out a series of short term recommendations to speed up standards setting and improve the efficiency of the process. In addition, the Green Paper calls for a fundamental overhaul of the European standards system by the end of 1991. The new system would put much more reliance on a network of sectorally-based European standards writing institutes, which would take decisions by majority vote.

Mutual Recognition of Member States Standards

Where European standards do not yet exist, products produced to national standards that meet the essential requirements of the EC directives or regulations will be guaranteed automatic access to the markets of all other member states.

3.2 The "Global Approach" to Testing and Certification

Testing and certification can create barriers to trade, irrespective of whether product standards have been harmonized. For example, products cannot enjoy free movement if the manufacturer has to have them rechecked by a different testing agency or certification body in each member state.

Therefore, under its "global approach" to testing and certification approved in December 1989, the EC is proposing a policy for mutual recognition of testing and certification by member states. This will involve sectoral recognition agreements on approved laboratory practices, together with enhanced mutual recognition of test data and certification marks by member states. A new European Organization for Testing and Certification (EOTC) will be established to provide a forum for all issues related to testing and certification.

3.3 Conformity Assessment Procedures

A particular EC directive will normally spell out a range of certification procedures whereby a manufacturer can demonstrate a product's proof of conformity with its requirements. These options - or modules - will vary with the degree of risk or danger presented by the product.

The range of possibilities includes:

- Self certification that the product meets essential requirements;
- Self certification based upon conformity to European standards;
- In-house quality assurance system;
- Third party certification.

At present only European-based organizations can provide third party certification.

Once a product is certified as meeting the essential requirements of the relevant directive (whether through self-certification or third-party testing), the manufacturer places the "CE" mark on his product and it, thereafter, should enjoy free circulation throughout the Community.

It is important to note that, although the use of the "CE" mark is the passport for free entry between member states, it does not mean that a particular product will meet with automatic consumer acceptance. Purchasers may also look for national marks or quality certificates as demonstrations of quality or conformity.

4. Canadian Concerns with EC Developments

From the Canadian perspective a number of concerns have emerged with respect to both the standards setting process and the EC's proposed arrangements with respect to testing and certification.

4.1 Concerns with the Standards Setting Process

The concerns of Canadian industry with the EC's standards setting process revolve around the following issues:

Lack of Transparency

In view of the ambitious scale of the reform underway in the EC, and the complexity and fluidity of the process, many small and medium-sized Canadian firms are having difficulty getting timely information on standards-related developments in the Community.

Lack of Effective Access to the Standards Setting Process

Although CEN and CENELEC have agreed to submit draft standards to standards organizations in both Canada (the Standards Council of Canada) and the US (ANSI) for comment, there is little evidence yet on the extent to which European standards setting will reflect inputs from non-EC interests.

Incompatible or More Stringent EC Requirements

Where EC standards are different from or incompatible with Canadian standards or testing requirements, the effect of these differences will be to raise costs for Canadian exporters seeking to pursue the EC market; in some situations the effect could be to exclude Canadian products from the EC market.

There is also some risk that harmonized new European standards could include more stringent health and safety requirements than may be necessary, which could act as barriers to trade.

Undermining of International Standards

In addition, while CEN and CENELEC have undertaken to use international standards where possible, there is concern that the heavy workload for 1992 could detract from their participation in ISO (the International Standards Organization) and IEC (the International Electrotechnical Commission), with the result that European standards will emerge in preference to international standards.

4.2 Concerns with Testing and Certification Procedures

With respect to the new European testing and certification procedures, the three critical issues are as follows:

Arrangements for Third Party Testing

When third party testing is required, the EC has indicated that it will only accept the results from an EC testing facility, unless a bilateral agreement has been negotiated with a third country. However, it will be some time before the Commission is in a position to enter into negotiations with third countries.

If Canadian firms are required to submit their products for testing and certification to European testing facilities, this could add considerably to the cost and difficulty of marketing goods to the EC.

The Type Approval Process

The EC relies heavily on the type approval system, rather than the self-certification system which is more normal in North America. Under a type-approval system, if an innovation is not covered by a regulation the product may not be type approved until an existing regulation is amended or a new one developed. The result could be that the adoption of the type approval process on an EC-wide basis could act to inhibit certain high technology exports from Canada to the EC.

Growing Importance of Quality Assurance

The EC's modular approach to certification places a strong emphasis on quality assurance (QA) programs. Canadian suppliers will find themselves under increasing pressure to adopt QA programs if they wish to expand their EC exports.

5. Recommended Actions by Canadian Business

Given the brisk pace of technical harmonization taking place in the EC and the broad-ranging implications of the Community's standards program, a number of major strategic actions should be considered by the Canadian business sector and by federal and Ontario governments in order to take full advantage of EC developments.

5.1 Identify Directives and Standards Which Could Affect Your Business

This Report identifies many of the major directives that could affect broad Canadian export sectors. In addition, Appendix D lists the regulated product groups that are covered by the new approach and other EC directives.

For further information on specific directives, excellent sources of information in Canada include the Department of External Affairs in Ottawa and the Standards Council of Canada (SCC).

Relevant contact points and phone numbers are provided in Appendix A, including those in the US and the UK.

5.2 Reassess Your Marketing Strategy in Europe

The creation of a new European-wide regime for standards and certification may necessitate a reassessment of a firm's marketing strategy. For example:

- The principle of mutual recognition may have implications for which member state is chosen as the point of entry into the EC market.
- Customer preferences may mean that the CE mark is not sufficient to meet with automatic customer acceptance. Purchasers may also look for national marks or quality certificates as demonstrations of product quality or conformity.
- If a product needs third party testing and certification, it will be necessary to establish which notified bodies, either inside or outside the Community, are accredited to perform such tests.
- Product redesign may be necessary to meet European standards.

5.3 Take Measures to Promote Your Interests in Brussels

Canadian firms can comment on draft CEN/CENELEC standards through the Standards Council of Canada. However, Canadian companies should be prepared to get actively involved in the standards setting process in CEN, CENELEC and ETSI to ensure that their interests are reflected.

While this will be more difficult for Canadian exporters than for Canadian firms with a business presence in the EC, there are direct and indirect options available to Canadian exporting firms. These include: working through a strategic partner in the EC; working through a trade association; or seeking the assistance of the Canadian government to influence developments in the EC.

5.4 Push for Reciprocal Testing Arrangements with the EC

Canadian firms should push for testing arrangements that will enable them to have their products, processes or companies certified in Canada for the EC market. Canadian business should push on two fronts:

- With respect to regulated European standards it will be essential for the Canadian government to negotiate a reciprocal government to government deal with the Community.
- With respect to voluntary standards the Commission has made it clear that these are to be negotiated by private sector agencies such as the CSA, which already has negotiated agreements with BSI in the UK and KEMA in the Netherlands.

5.5 Consider Adoption of a Quality Assurance System

It is inevitable that, over the next few years, more and more Canadian exporters to the EC will have to put in place QA programs if they wish to continue to sell into the EC.

The Quality Management Institute (a division of the CSA) can assist Canadian firms to become certified to European EN 29000 standards.

1. INTRODUCTION

Background

Standards harmonization, along with the mutual recognition of procedures for testing and certification, is a key component of the European Community's 1992 single market program. The EC's objective is to eliminate arbitrary technical barriers that restrict products from being freely marketed throughout the Community.

There are three types of technical barriers:

- The first results from differences in national regulations. These legally binding rules are generally enacted in order to protect health, safety, or the environment.
- The second type of barrier is caused by differences between national industrial standards (DIN in Germany, Afnor in France and BSI in the UK, etc). These voluntary standards are not legally binding but nevertheless can act as barriers to trade.
- The third type of barrier can be caused by the testing and certification procedures. A barrier to trade occurs every time an importing country requires certification additional to that required in the country of origin. The EC effort to harmonize standards and technical regulations is a very ambitious one. Almost 30% of the 285 directives that comprise the 1992 program are standards-related.

Standards harmonization in the EC poses significant opportunities and risks for Ontario and Canadian producers. In principle, the removal of technical barriers to trade within the EC holds out the opportunity for Canadian products to be accepted for sale throughout the Community if they meet requirements in any one member state. However, there is still considerable uncertainty about the practical implementation of procedures for the treatment of products from third countries, such as Canada.

Purpose of this Report

The overall Report has the following objectives:

- To identify potential changes created by the Europe 1992 standards setting, certification and enforcement mechanisms.
- To examine the implications of these changes for trade, technology and investment opportunities with the EC in a number of key Ontario industry sectors, with particular attention to the impact on small and medium-sized enterprises (SMEs).
- To identify appropriate strategic actions by governments and the business community in Canada and Ontario, in response to EC standards-related developments.

Outline of the Report

The Report is set out in seven sections, including this introduction:

Section 2 describes the main features of the new EC legislation with respect to standards-setting, testing and certification.

Section 3 outlines the standards-setting process in the EC, in particular the roles played by the European standards bodies, such as CEN (the Committee for European Standardization), CENELEC (the Committee for Electrotechnical Standardization) and ETSI (the European Telecommunications Standards Institute). It also outlines the reforms proposed by the Commission's recent Green Paper to speed up the standards writing process in Europe.

Section 4 deals with the new testing and certification procedures that will result from the EC's "global approach" and its modular certification procedures.

Section 5 sets out the standards directives that will affect the major Canadian export sectors to the EC and identifies their potential impacts on the different sectors.

Section 6 addresses the overall benefits and concerns for Canada that will result from the EC's standards program.

The final section makes recommendations about specific actions that could be taken by Canadian business in response to EC standards-related developments.

The Report also contains a number of appendices which provide information on individuals interviewed, background material on the EC directives and a lists of contact points and publications for further information.

Acknowledgments

The Report was written by Roger Hill of Hill Sloan Associates Inc. Particular mention should be made of the assistance and guidance provided by Keith Aird and Mitch Vlad of the federal Department of External Affairs, Diane Thompson of the Standards Council of Canada, Larry Rogers of the Quality Management Institute, and Fernando Traficante of the Ontario Ministry of Industry, Trade and Technology.

2. EC LEGISLATION

2.1 Background

Most EC countries have their own technical regulations which set health, safety and environmental quality requirements for goods sold in their national markets. In addition, there are differences in voluntary product standards between member states, and testing and certification procedures are often not recognized from one member state to another.

The result of differing technical regulations and national standards is the fragmentation of the Community market, which adds significantly to the cost of production in many EC industrial sectors and results in higher prices for EC consumers.

The original approach to dismantling these technical barriers to intra-Community trade was an attempt to harmonize national regulations across the Community. However, this proved to be a very difficult and slow process, with the result that progress was very limited.

Consequently a "new approach" to the reduction of technical barriers was adopted. Community directives with respect to technical harmonization would no longer define the technical details; they would only set out the "essential requirements" with respect to health, safety and the environment.

2.2 The Failure of the Old Approach

In the late 1960s the European Commission began an ambitious technical harmonization program. Progress was so slow that over the next fifteen years the EC had adopted only about 10 technical directives a year.

The failure of the old approach to technical harmonization reflected:

- Time-consuming and cumbersome procedures;
- The problems of getting unanimous agreement;

- The focus on excessive product conformity;
- The neglect of the problems of certification and testing; and
- A lack of political interest by Ministers.

It is not surprising that by the early 1980s there was profound disappointment and frustration with the progress that had been achieved. Therefore, in 1985, a "new approach" to harmonization and standardization was initiated.

2.3 The New Approach to Harmonizing European Standards

The main elements of the new approach are:

Harmonization of Essential Standards

EC will normally only lay down essential Community-wide legislative requirements for health, safety and environmental protection. However, mandatory EC standards will also be developed in high technology areas, such as telecommunications, information technology and biotechnology.

EC directives or regulations will spell out "essential requirements". To date, a number of directives have already been agreed upon. These cover simple pressure vessels, toy safety, construction products, electro- magnetic compatibility, machine safety, personal protective equipment, weighing instruments, gas appliances and certain electromedical equipment. Other directives are under discussion, with more to follow. A list of new approach and other directives is set out in Appendix D.

Detailed specifications are then developed by the European standards bodies, such as CEN (the Committee for European Standardization), CENELEC (the Committee for Electrotechnical Standardization) and ETSI (the European Telecommunications Standards Institute). It is important to note that EFTA countries are members of these standards bodies; the US and Canada are not.

Mutual Recognition of Member States Standards

Where European standards do not yet exist, products produced to national standards that meet the essential requirements of the EC directives or regulations, will be guaranteed automatic access to the markets of all other member states.

This principle of mutual recognition reflects the landmark 1979 ruling by the European Court of Justice in the "Cassis de Dijon" case, namely that products lawfully produced and marketed in one member state should be given free access throughout the EC.

Notification of New Standards

The 1983 "mutual information" directive has been expanded to require member states to notify the Commission (and other member states) of proposed new standards or regulations. The Commission is empowered to temporarily suspend a standard if it could act as a barrier to trade or if a European standard would be preferable.

2.4 Sectoral Standardization Initiatives

The other standardization measures that are part of the 1992 initiative are grouped into various industry sectors and in general are primarily concerned with health, safety and type approval. These include:

- Directives to bring about a comprehensive EC type approval for passenger cars, tractors and agricultural machinery. This will allow a vehicle approved in one member state to be marketed in another without having to obtain new type approval.
- The new strategy for food harmonization moves away from compositional directives to concentrate instead on setting general food safety and hygiene standards and establishing a more informative system of food labelling.

- The construction products directive is based on the "new approach" principles. All construction products must be fit for their intended use and meet other essential requirements concerning stability, safety in the case of fire, hygiene, safety in use, protection against noise and economy of energy.
- Rapidly changing information technologies have given rise to a range of new information services. The Community proposes to ensure that differing technical standards do not prevent the development of a strong single European market for both service providers and equipment suppliers.

2.5 Environmental Legislation

In 1972, the Community initiated an Environmental Action Program. Since then, more than 120 legislative measures have been adopted covering different aspects of the environment.

In a number of instances the EC's environmental legislation sets out standards (primarily noise and air quality standards) that have to be met by products offered for sale in the Community. For example:

- The fight against noise pollution at the Community level has focussed on sound levels for specific products. So far, the Council has adopted directives harmonizing maximum noise levels for specific products such as motorcycles, subsonic aircraft, tractors, lawn mowers, and building machinery.
- With respect to air quality standards, imports of CFCs from all third countries not party to the Montreal Convention are prohibited as of January 1, 1990. The Commission has announced that it has drawn up a further proposal to eliminate the import of CFCs by the end of the century.
- The new directive on small car emissions provides for mandatory emission standards (comparable to US standards) after 1992. Voluntary EC emission standards for medium and large cars are also expected to be tightened by 1993. The Commission intends to dramatically tighten the standards for particle emission in all diesel automobiles.

- The maximum lead content of gasoline must be reduced from 0.4 grams/litre to 0.15 g/l. In 1993, all new cars sold in the Community will have to run on unleaded gasoline.

2.6 The Global Approach to Certification and Testing

Testing and certification can create barriers to trade because, irrespective of whether product standards have been harmonized, the products themselves cannot enjoy free movement if the manufacturer has to have them rechecked by a different testing agency or certification body in each member state.

Therefore, the EC is proposing a policy for mutual recognition of testing and certification by member states. This will involve sectoral recognition agreements on approved laboratory practices, together with enhanced mutual recognition of test data and certification marks by member states.

The "Global Approach to Certification and Testing" was approved in a Council Resolution on December 21, 1989.

In the regulated areas (i.e: where manufacturers have a legal obligation to meet certain EC requirements for the purpose of health, safety or the environment) the certification infrastructure will be supervised closely by the Commission.

Significant features of the "Global Approach" are:

Conformity Assessment Procedures

Each directive must set out conformity assessment procedures to enable public authorities in the EC to ensure that products placed on the market conform to essential requirements, especially in regard to the health and safety of users and consumers.

Specific directives should, wherever possible, offer various combinations of certification procedures (or modules) in order to leave as wide a choice to the manufacturer as possible.

The Role Of Notified Bodies

For the purposes of third party certification each member state would be required to nominate "notified bodies", each of which would be accredited by a national accreditation system. Accreditation of a notified body would normally be based on conformity to EN 45000.

The "CE" Mark

Once a product has been declared or certified as meeting the essential requirements of the relevant directive, the manufacturer may place the "CE" mark on his product and, thereafter, it should enjoy free circulation throughout the Community.

3. THE STANDARDS SETTING PROCESS IN THE EC

3.1 Background

Voluntary industrial standards related to product quality and compatibility will continue to be set by national standards bodies, such as DIN in Germany, Afnor in France and BSI in the United Kingdom.

With respect to the development of harmonized European standards, the Commission's new approach, at present, assigns a crucial role to the three European standards setting bodies, namely the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI).

However, the Commission has become increasingly concerned with the slow pace of standards writing under CEN, CENELEC and ETSI. Therefore, a recent Green Paper, recommends that a new European standards system be put in place by the end of 1991, which would put much more reliance on a network of sectorally-based European standards writing institutes. In the meantime, the Green Paper proposes a series of short-term measures to speed up standards setting and improve the efficiency of the existing process.

3.2 National Standards

The national standards institutions are the main instruments of standardization policy in the individual European countries.

Although there are great similarities in the statutes and operating methods of these bodies, they differ significantly in their size, output, and resources. This is demonstrated in the table below.

Despite the new emphasis on European standards, a large number of national standards continue to be produced. In fact national standards are being written at 10 times the rate of European ones.

Major National Standards Organizations in the EC: 1986

Country	Institution	Staff	# of Standards	
			Annual	Cumulative
Germany	DIN	600	1,400	26,000
Spain	AENOR	70	850	2,300
France	AFNOR	450	1,100	13,500
Italy	UNI	50	270	6,500
UK	BSI	600	650	10,000

Source: Nicolas 1988, citing ISO and CEN

3.3 Development of European Standards

The European Commission requests the relevant European standards body (CEN, CENELEC or ETSI) to develop harmonized European standards either in areas covered by the new approach directives or in subjects which are critical to the Community's industrial policy, particularly in new technologies.

A Commission request for a European standard is intended to accelerate standardization work in areas of high priority. The acceptance of such a request by the particular European standardization body **imposes a standstill on all related national standardization work**, thus making technical expertise available for European work.

The Commission does not intervene in the drawing up of the standards except to recall, where appropriate, the essential requirements of an EC directive and to refer to relevant international standards.

3.31 CEN and CENELEC

CEN and CENELEC are not EC institutions, but associations whose members are the eighteen national standards organizations or electrotechnical standardization committees in both the EC and EFTA.

The work of these two standardization bodies is organized through national delegations, each national member body being responsible for the representation of national interests at the European level and for consultation at the national level concerning proposals for a new European standard. CEN and CENELEC do not provide for the direct participation of interested parties in their work except through their national standardization bodies. European-level professional organizations or industrial associations may, however, be given observer status for European standardization of particular interest to them.

Although their head offices are in Brussels, the work of CEN and CENELEC are largely carried out by committees with responsibility for specific product categories, and these are based in individual member states. For example the committee for pressure vessels is in the UK; the one for ceramics is in Italy; the one for containers in West Germany; and the one for toys is in Denmark.

In order to avoid possible delaying tactics by special or national interests, CEN has had to reorganize its voting rules from unanimity to a weighted majority voting procedure. However, it should be noted that if more than 3 members vote against a proposal, it cannot be adopted under existing CEN rules.

The normal process for the adoption of a European standard is as follows:

- New work items are proposed by a member body, or by the Commission, or a European industrial federation;
- Agreement to proceed is given by the Technical Board of CEN/CENELEC;
- If an international standard already exists, a preliminary questionnaire is sent to members. If approved, CEN/CENELEC proceeds to a formal vote; if not, the item is referred to a technical working group;
- If there is no appropriate international standard, the work item is allocated to a Technical Committee for preparation of a draft;
- On completion of the draft, a six month public enquiry is conducted in each member country;
- Comments received are analyzed by the Technical Committee, before a formal vote (a two months procedure) on a draft European Standard;
- If adopted, the European standard is then published in each member country as a national standard.

Different Types of CEN/CENELEC Standards

CEN standards are published in one of the following forms:

European Standard (EN)

The EN must be implemented without alteration at the national level and given the status of a national standard. Any conflicting national standard must be withdrawn.

The EN implies that the identical text is applicable in all member states.

Harmonization Document (HD)

The HD must be implemented at the national level either by issue of a corresponding national standard or, at a minimum, by the public announcement of the HD number and title. In both cases no conflicting national standard may continue to exist.

However, the HD also allows national deviations under special conditions: to allow for a national legal or regulatory obligation or to allow for a technical problem.

European Pre-standard (ENV)

An ENV may be established as a prospective standard for provisional application in technical fields where the innovation rate is high or where there is an urgent need for guidance.

CEN members are required to make the ENV available at the national level in an appropriate form and to announce its existence in the same way as for ENs and HDs.

Any conflicting national standards may be kept in force until the ENV is converted to an EN. The lifetime of an ENV is normally limited to three years. At that point the Technical Board can decide to convert the ENV to an EN after a formal vote; extend the ENV for another two years; replace the ENV with a revised ENV; or withdraw the ENV.

Involvement of Non-European Countries in CEN/CENELEC Process

Interested parties in the European standardization process, including those outside the Community, are informed about progress and can make their views known at a number of stages in the procedure.

New CEN/CENELEC work items are publicized in a monthly Review of Activities. CEN/CENELEC are prepared to receive written contributions, relevant to the proposed work, from non-European standardization bodies that are members of ISO/IEC.

A draft European standard, once agreed at the technical level, is published for comment. Copies of the draft standards are also made available to ISO/IEC member bodies. CEN/CENELEC is

prepared, if comments are important enough and if a technical discussion might be advantageous, to organize meetings between those having raised comments and the relevant technical experts of CEN/CENELEC.

3.32 ETSI

ETSI has a different kind of membership and different working methods to CEN/CENELEC. Membership is open to all relevant organizations with an interest in telecommunications standardization which belong to a country within the geographical area of CEPT (the European Confederation of Post and Telecommunications Administrations). This includes network operators, manufacturers, users and research bodies. There are over 200 member organizations in ETSI and over 30 observers.

Members may participate directly in standardization work organized at the European level. The process of consultation, public enquiry, voting and publication of a European telecommunications standard is similar to that followed by CEN/CENELEC and is carried out by the relevant national standardization body.

ETSI has a permanent secretariat located in Sophia Antipolis, near Nice in France. ETSI is governed by a General Assembly, while the production and approval of standards takes place under the direction of the Technical Assembly.

The development of standards involves two types of groups: Technical Committees and Project Teams. Technical Committees are composed of experts who provide a forum for consensus-building on a draft standard to be submitted to the Technical Assembly. The Project Teams are groups of experts that work under the guidance of Technical Committees and prepare draft standards in response to specific technical problems.

The ETSI Agenda

Specific ETSI Project Teams have been or will be formed to address the following issues:

- PT1: ISDN Basic Access
- PT2: PSTN Basic Access
- PT3: Terminal Adaptor
- PT4: Modems
- PT5: Facsimile Group 4 on ISDN
- PT6: X.32 Access
- PT7: ISPBX Interconnection
- PT8: Equipment for Private Mobile Radio Service
- PT9: ISDN Supplementary Services
- PT10: Digital Cordless Telephone
- PT11: Digital Paging Systems

ETSI has taken over from CEPT the standards program which leads to the European telecommunications standards (NETs). ETSI has set as a target the production of 100 new standards per year.

Involvement of Non-European Organizations in the ETSI Process

One feature that distinguishes ETSI from CEN/CENELEC is that non-European organizations concerned with telecommunications may be invited to participate as observers in the technical work of the organization.

In particular, the Technical Committees can involve participants who are not members of the Institute.

An agreement has also been concluded between ETSI and ANSI (the US standardization body) on the exchange of information about their respective standardization work.

3.4 The Commission's Green Paper Proposals

It has been estimated that, as a result of the 1992 program, CEN, CENELEC and ETSI will be involved in developing about 1100 new European standards.

The Commission has become increasingly concerned that the standards writing procedures under CEN, CENELEC and ETSI are proving inadequate to get all these new standards ready by the end of 1992. The completion of the single market still requires the writing and adoption of 800 European standards, which is equivalent to about one standard per day between now and January 1, 1993.

Therefore, in a Green Paper tabled in October 1990, the Commission recommends important changes in the way European standards are set. The Green Paper calls for a fundamental overhaul of the European standards system by the end of 1991. The new system would put much more reliance on a network of sectorally-based European standards-writing institutes, which would take decisions by majority vote. Under the proposed system, there would be:

A European Standardization Council

This would be composed of representatives from the concerned entities, notably the Commission, the EFTA Secretariat, and the presidents of the European standards bodies.

The Council would be responsible for the strategic direction of the European standardization system. It would establish common rules and principles for all European standards bodies; it would develop methods of arbitration in the event of disputes between standards entities; and would determine procedures for the admission of new European standards bodies.

A European Standardization Board

The Board would be the executive arm of the Council and would manage and coordinate the European standardization system on behalf of the Council. It would be made up of representatives from all European standards institutes.

European Standards Bodies

These are bodies organized to carry out standards work at the European level and would be recognized by the Council as responsible for developing standards in their particular sectors.

National Standards Bodies

These would be responsible for carrying out certain tasks for the European standards bodies, such as public surveys. They could also assume the secretariat of European-level technical committees, sub-committees and working groups.

Until such a system is created, the Green Paper also sets out a series of short-term recommendations to speed up standards setting and improve the efficiency of the existing process:

- The use of "project teams" made up of industry experts to accelerate the drafting of standards;
- Greater use of industry based associations to act as "associated standards bodies" on behalf of CEN and CENELEC;
- Use of qualified majority voting for approving standards;
- Use of advanced technology communications to accelerate discussions;
- Shorter timeframes for public inputs; and
- Direct applicability of adopted European standards without waiting for them to be transcribed into national legislation.

The Commission has set a deadline of January 1991 for receiving comments on the Green Paper. It is likely, however, that the Commission's proposals will be resisted strongly by the national standards organizations. Some experts doubt whether this is the appropriate time to alter the way in which European standards are drawn up, since changes to the system could slow progress even further.

4. EUROPEAN CERTIFICATION AND TESTING PROCEDURES

4.1 Background

Mutual recognition by the EC member states of the procedures used to assess conformity of a product to a standard is another important step toward removal of technical barriers to trade within the Community. Without such recognition, a manufacturer can be faced with serious delays and costs in introducing a product onto the market, even if it has followed a given standard.

The Community is in the process of developing a comprehensive policy which confers clear rights for manufacturers with respect to testing and certification throughout the EC.

Negotiations on mutual recognition of testing facilities in Europe will take place directive by directive as the European standards come into force. The first Directive to come into force - that for pressure vessels - took effect on July 1, 1990.

Clearly, familiarity and compliance with European certification and testing procedures will be extremely important for manufacturers who wish to market their products and services in the Community.

4.2 Methods of Satisfying the Essential Requirements

While, the EC's "essential requirements" directives are mandatory, the CEN/CENELEC/ETSI technical requirements are voluntary. This means that a manufacturer must be able to prove that its regulated product or service conforms to the EC directive but not necessarily to the CEN/CENELEC/ETSI standard.

The European standards which are developed on the basis of the essential requirements of an EC directive represents only one option open to manufacturers to demonstrate conformity to those requirements. The advantage of following European standards is that this constitutes a fast track to the EC market, insofar as it always gives rise to accelerated procedures for demonstration of conformity to essential requirements, often without third party testing.

Nevertheless, other options, such as conformity to national standards or to no standards at all, may be chosen. In the latter case the manufacturer will have to prove, usually by third party certification, that its product conforms to the essential requirements.

4.3 The Modular Approach to Attestation

A particular EC directive will normally spell out a range of options whereby a manufacturer can demonstrate a product's proof of conformity with its requirements. These options - or modules - will vary with the degree of risk or danger presented by the product.

The range of possibilities (see Appendix F) includes:

- Self-certification that the product meets essential requirements;
- Self-certification based upon conformity to European standards;
- In-house quality assurance system (based on EN 29000);
- Third party certification.

4.4 Notified Bodies

Where third party verification of the manufacturer's claim of conformity is required, the third party is referred to as a "notified body".

At present only European-based organizations can qualify as "notified bodies". Such organizations could include testing laboratories, operators of certification systems, or even governmental agencies. For each product subject to Community directives each member state will designate and/or accredit a notified body. Each notified body will have to be structured and operate in compliance with the Community's EN 45000 series of standards.

4.5 The "CE" Mark

Once a product is certified as meeting the essential requirements of the relevant directive (whether through self-certification or third-party testing), the manufacturer places the "CE" mark on its product and, thereafter, it should enjoy free circulation throughout the Community.

It is important to note that, although the use of the "CE" mark is the passport for free entry between member states, it does not mean that a particular product will meet with automatic consumer acceptance. Purchasers may also look for national marks or quality certificates as demonstrations of quality or conformity.

4.6 The European Organization for Testing and Certification

The Council in its Resolution of December 21, 1989 endorsed the establishment of a new organizational framework in Europe for testing and certification arrangements in the private sector. This reflects the fact that, whereas European standards bodies have existed for over 20 years, no similar structure exists for testing and certification.

The role of the European Organization for Testing and Certification (EOTC) would be to provide a forum for all issues related to testing and certification. Once fully operational, EOTC would be expected to:

- Encourage, foster and manage the development of European certification systems and of mutual recognition arrangements;
- Provide the organization for the voluntary sector;
- Provide and exchange information; and
- Assist the Commission in the field of conformity assessment, including mutual recognition agreements with third countries.

It is proposed that the Organization will be made up of:

- A Council composed of representatives of the conformity assessment community in each member state, as well as consumer organizations, trade unions, industry, and the European standards bodies;
- Specialized Committees in areas such as calibration, testing certification, quality assurance, and inspection;
- Sectoral Committees; and
- Agreement Groups.

CEN and CENELEC will provide a specific administrative infrastructure for the EOTC.

Participation in the EOTC framework would not be compulsory and there would be nothing to stop sectors working out certification agreements without reference to EOTC.

4.7 The CERTIFICATE Database

In order to ensure easy access to information concerning technical regulations, standards and procedures relating to testing and certification, the Commission is financing the creation of a European database. The database, called CERTIFICATE, will contain information on which products have to be certified, by whom, how, and what procedures have to be followed. The database will be constantly updated and will be accessible to non-Community firms.

4.8 Testing and Certification Arrangements for Voluntary Standards

With respect to voluntary standards used in the Community, mutual recognition and other arrangements will be left to the private sector, albeit with considerable encouragement from the Commission.

The "Global Approach" to testing and certification represents an important first attempt to reduce trade barriers that result from the use of voluntary standards.

The Commission has made two important proposals with respect to testing and certification of voluntary standards:

- The first is a series of measures to enhance the transparency and competence of testing agencies, inspection bodies and certification bodies. These include promotion of the European standards for quality systems and for the competence of test laboratories and certification bodies, and the greater use of national systems for the accreditation of test laboratories and certification bodies.
- Second, the European Organization for Testing and Certification (EOTC) is supposed to encourage voluntary agreements for the mutual recognition of testing and certification, with the emphasis on the needs of different product sectors.

However, arrangements for the mutual recognition of certification and testing would have to be concluded by the private sector.

There is no EC marking system with respect to voluntary standards (The CE mark only applies to the essential requirements directives). Therefore, national marks will continue to prevail in terms of customer acceptance.

4.9 Testing and Certification for Foreign Manufacturers

Arrangements for the mutual recognition of testing and certification agencies in third countries will differ significantly between the regulated and voluntary areas:

Regulated Areas

The certification procedure is fully open to foreign companies on a non-discriminatory basis. Thus a Canadian supplier, once its product is certified (even where the directive permits self-certification) can fix the CE mark and the product can enjoy free circulation throughout the Community.

However, in order for the Community to recognize testing and certification done in Canada, there will need to be an agreement on the mutual recognition of testing and certification signed between Canada and the Commission.

The Commission is expected to receive its mandate later in 1990 to enter into negotiations with third countries.

Any international agreement with the Community would have to satisfy three conditions:

- The first would be that the foreign testing and certification bodies were competent and were appropriately accredited by a national accreditation system. While meeting EN 45000 would not be mandatory for a foreign testing organization, it would be helpful.
- The second element would be a requirement for reciprocity - ie European notified bodies should also be able to test and certify conformity to Canadian standards.
- The third element would be a requirement that mutual recognition agreements were confined only to the bodies designated in the agreement.

Short of a full-fledged agreement on mutual recognition for testing and certification, there would also be the possibility for a notified body in the EC to subcontract work to a testing laboratory in a third country, so long as this was done within the bounds described by the EN 45000 and as long as the notified body was responsible for the certification. The limits to such subcontracting have yet to be defined by the Council.

There remain some areas still subject to regulation by member states since regulations have not yet been fully harmonized at the Community level. Food is the most obvious example of this. Here the Community may allow member states to pursue bilateral certification agreements with third countries under close guidance from the Commission.

Voluntary Areas

In the voluntary area it will be up to Canadian certification and testing bodies to negotiate directly with sectoral agreement groups set up under EOTC or operating independently. There would appear to be no reason why Canadian testing and certification bodies should not arrive at mutual recognition agreements with agencies in the more advanced member states before full participation by bodies from all member states.

4.10 Progress to Date

The progress on testing and certification is moving even more slowly than that on standards, and may ultimately prove to be a bigger problem.

Testing and certification was recognized as a problem in Europe more than 20 years ago, but it was only in 1990 that the agreement to set up the EOTC was signed.

One of the challenges is to develop a European mark of quality which is trusted throughout Europe. In the meanwhile, there are the vested interests of the certification bodies to be taken into account, as well as the differing requirements of member states.

5. SECTOR SPECIFIC ISSUES

A total of about 80 standards-related directives have been proposed by the EC Commission as part of the 1992 single market program, over half of which have already been adopted into law.

EC standards-related developments could have particular significance for Canadian exporters in a number of sectors. These are described in the following sections.

5.1 Forest Products

Significant EC Standards Legislation Affecting the Sector

Canadian exporters of forest products to the EC could be affected by a number of standards-related issues. These include new construction products standards; phytosanitary issues; and environmental regulations.

The Construction Products Directive

The main objective of the Construction Products Directive is to eliminate barriers to trade caused by national rules and regulations, while at the same time maintaining acceptable levels of health and safety.

The directive spells out the essential requirements of all materials to be used in construction. These are aimed to ensure that construction products are used only "if fit for that purpose" and that the construction in which they are incorporated can, if properly designed and built, satisfy six basic needs:

- Mechanical resistance and stability;
- Safety in case of fire;
- Hygiene, health and environment;
- Safety in use;

- Protection against noise; and
- Energy saving and heat retention.

CEN has the responsibility to develop appropriate European standards. This is being done through the development of Eurocodes, which deal with the mechanical strength of structures and their stability. Eurocode 5 which deals with "Common Unified Rules for Timber Structures" is of particular interest to Canadian exporters of lumber and other structural wood products.

The working parties drafting the new CEN standards for structural timber have a program that will lead to definitions, among others, for:

- Various test methods;
- Standards and sizes;
- Moisture content and tolerances in shrinkage;
- Principles of stress grading; and
- Mechanical Joints.

Eurocode 5 is likely to be operative in 1991 at the latest.

Phytosanitary Requirements

The pinewood nematode is a microscopic organism which the European Community perceives as a threat to its forests. Based on this concern, EC plant health authorities are considering new regulations to control imports of green softwood lumber from Canada.

Environmental Regulations

As environmental issues are becoming more important in the EC, they are beginning to impact on Canadian forest product exports to Europe.

Certain European countries are already demanding better control of lumber which is imported with anti-stain chemical treatments that are believed to be toxic - in particular chlorophenate-based sprays.

In addition, EC consumers are demanding greater use of recycled fibres in newsprint and other paper products. An EC ban on pulp produced by processes exceeding certain emission requirements is a possibility that cannot be ignored.

Implications for Canadian Suppliers

The EC is Canada's second largest market for forest products after the US. In 1989, total Canadian forest product exports to the Community were worth more than \$3.3 billion.

The principal Canadian forest product export products to the EC are, in order of their sales value, wood pulp, softwood lumber, newsprint, specialty papers and plywood.

On balance, the development and acceptance on a Community-wide basis, of product standards and other regulations consistent with Canadian supply capability should be positive. It could open up a huge export market of 325 million people to Canadian industry. In particular, the modernization of building regulations throughout the EC could lead to greater opportunities for the use of wood products in construction.

Nevertheless, certain EC standards related developments are of concern to Canadian suppliers of forest products. For example:

- One risk for Canadian producers of wood products is that the resulting new European standards and grading rules could incorporate European-focussed requirements that Canadian shippers might find difficult or uneconomical to meet. Since the EC is a major market for Canadian wood products, any measures that caused a disruption of trade could have a major impact on Canadian production.
- If, as a response to the pinewood nematode issue, the EC decides to permit entry only to lumber that has been kiln dried, this could have major implications for Canadian lumber exporters. At present 90% of all lumber from Canada enters the Community as green lumber.

- The growing importance of environmental issues in the EC means that European markets for Canadian exporters of pulp and paper products could remain in flux for some time to come, and this could have important consequences for Canadian producers.

5.2 Telecommunications Equipment

Significant EC Standards Legislation Affecting the Sector

The directives that relate to standards for telecommunications equipment and services are part of a comprehensive EC policy on the telecommunications sector.

The telecommunications market has been a particular target for the Commission. A modern telecommunications infrastructure has been identified as of major importance for Europe's economic future. In addition, another motive for the extensive restructuring of the EC's telecommunications sector reflects the changing economics of the industry. Development costs for major telecommunications products - such as central office switches - have accelerated rapidly. Without a unified European market, EC suppliers will be unable to offset or recoup rising product development costs and compete in the world markets of the 1990s.

Of particular significance for Canadian firms are the standards-related provisions in the excluded sector directive; the terminal equipment directives; the directive on open network provisions; and directives that harmonize standards for new telecommunication products, such as cellular radio.

The Excluded Sectors Directive

The excluded sectors directive (ESD), extends the Community's purchasing rules to include entities in the formerly excluded sectors, namely water, energy, transport, and telecommunications.

In the telecommunications sector the directive covers entities providing or operating a public telecommunications network or providing one or more telecommunications services to the public.

The ESD is to take effect as of January 1, 1993 in the case of most member states. Spain has three extra years to comply (to January 1, 1996) and Greece and Portugal have five extra years (to January 1, 1998).

The ESD requires technical specifications to be defined by reference to European standards or by reference to common technical specifications or European technical approvals, where these exist.

There are various permitted derogations from this rule, including one which provides a temporary exemption when a purchaser can demonstrate that a particular European specification would oblige it to acquire supplies incompatible with equipment already in use or would entail disproportionate cost or technical difficulties.

In the absence of European specifications, technical specifications should as far as possible be defined by reference (in descending order of preference) to other standards having currency in the Community, such as national standards which implement international standards, other national standards, or any other standard.

Performance specifications and standards that specify functional requirements should be used unless there are sound reasons for not doing so.

Contracting entities must make available to interested suppliers those technical specifications that are used regularly or will be used for planned procurement.

Telecommunications Terminal Equipment Directives

Terminal equipment is defined as "equipment directly or indirectly connected to the termination of the public telecommunications network to send, process or receive information".

Under a 1988 directive member states must publish the technical specifications that the terminal equipment must meet in order that equipment from another member state can be adapted to meet the necessary specifications. Consumers must be allowed access to terminal/network contact points and to the technical data relating to such contact points.

Another directive proposing the full mutual recognition of type approval for terminal equipment was submitted to the EC Council of Ministers in July 1989.

The objective of the proposal is the harmonization of procedures in the fields of testing, marking, certification and quality control of terminal equipment.

Under the proposal, terminal equipment would be examined by third party organizations to ensure that it complies with Community technical standards. Approval would lead to the issue of a certificate. An approved terminal would then carry a mark of conformity (a "CE" symbol) and would be free to be marketed throughout the Community without further procedures at the national level.

Responsibility for drawing up the Community standards has been given to the European Telecommunications Standards Institute in cooperation with CEN and CENELEC.

The "Open Network Provision" Directive

At present the provision of pan-European telecommunication services, especially by private companies, can be made impossible by the absence of harmonized technical interfaces, divergent conditions of use, or discriminatory tariffs. The Open Network Provision (ONP) directive aims to eliminate these divergences through harmonization. The major features of the ONP directive are:

- Technical interfaces will become the subject of voluntary European standards to be adopted by the European Telecommunications Standards Institute (ETSI). Service providers who comply with these standards will have the advantage of being able to offer their services throughout the Community.
- If these voluntary standards do not result in the interoperability of services between member states and improve freedom of choice for users, the Commission may introduce mandatory compliance, especially with respect to basic data services, such as packet switching and the integrated services digital network (ISDN).

The Open Network provision directive should enter into force in mid-1990.

The ONP is a framework directive, which will be followed by a series of specific directives on other services. There will be specific directives for leased lines and voice telephony, for example. As for other services, directives will be examined with a view to adopting them in 1992. By January 1, 1991, technical interfaces and service features relating to packet-switched data transmission and the ISDN will be established, and the directive will be adopted by January 1, 1992.

Cellular Radio

The directive seeks to coordinate efforts to replace the current incompatible national mobile telephone systems with a standardized European-wide system for cellular digital mobile communications. Equipment and operating specifications will be standardized within the Community by 1991.

Implications for Canadian Suppliers

The EC market for Canadian telecommunications products was worth \$109 million in 1989. The EC is the second largest export market for Canadian telecommunications equipment after the US.

In addition, a number of Canadian firms have set up manufacturing operations in the EC. These include Northern Telecom, Mitel, Gandalf, and Newbridge Networks.

In the past Canadian firms have been disadvantaged by market access restrictions for telecommunications terminal equipment created by the standards, testing and certification procedures in individual member states:

- The cost of meeting different national standards in the EC has been high for Canadian suppliers. For example, Northern Telecom has spent between \$1 and \$5 million every time that it takes its private branch exchange (PBX) range through the redevelopment and approvals process needed to enter a new European market.

- In some countries, notably France and Italy, companies have been required to fulfil certain residency requirements before they could even enter the approvals process. Although the problem has often been surmounted by forming a relationship with a local distributor or agent, this has proven to be a time consuming and costly process.
- In some member states, even when a product has been certified, this may not constitute permission to connect to the telecommunications network. This permission has had to be gained separately from the PTT.

Therefore the measures to harmonize standards setting, testing and certification procedures in the EC telecommunications market should have a positive impact on Canadian suppliers.

In particular, the terminal equipment directives will have a positive effect on Canadian manufacturers of equipment such as PBXs and multiplexers, as well as providers of services that use this equipment. It should benefit both Canadian exporters as well as Canadian firms that have established production facilities in the EC.

5.3 Automotive Products

Significant EC Standards Legislation Affecting the Sector

The EC automobile market has been highly fragmented due in large part to national technical barriers that have undermined the creation of a single market. These barriers have included:

- A lack of standardization of national technical requirements;
- Widespread differences in exhaust emission requirements of member states which can lead to costly modifications being necessary before a car fits the requirements of an importing state; and
- Various national requirements for the standard equipment of vehicles, such as yellow headlamps bulbs in France, dim dip headlights in the UK, etc.

In order to promote the free movement of automobiles and parts throughout the Community, directives to promote EC type approval accounts for a very substantial amount of the new EC legislation affecting motor vehicles. The 1992 program also includes a group of new directives that harmonize automobile emissions standards.

EC Type-Approval for Motor Vehicles and Trailers

The EC type-approval process will abolish the 12 national type-approvals for motor vehicles, subassemblies and components and replaces them with one Community-wide system. This will simplify the administrative burden for the industry.

EC type approval refers to the procedure whereby a member state certifies that a vehicle type (or a subassembly or part) satisfies the technical requirements of appropriate directives. Since a member state must approve all vehicles and parts that satisfy the requirements in the appropriate directives, and a certificate of conformity must be accepted by all other member states, this procedure facilitates the free circulation of automobiles and parts within the Community.

Technical Harmonization Directives

A significant number of technical harmonization directives related to automobiles have already been adopted. These include directives related to:

- Braking devices;
- Doors;
- Fog lamps, headlamps, direction indicators;
- Head restraints;
- Fuel tanks;
- Mirrors;

- Seats and seat belts; and
- Wiper/washer systems, etc..

EC Type-Approval for Tyres and Safety Glass

The Commission has put forward proposals to bring into line the different national type-approvals for motor vehicle tires and for safety glass used in motor vehicles.

Under the proposals member states must grant EC marks for tires or safety glass conforming to the requirements of the directives. Member states could not prohibit or restrict the placing on the market products bearing the EC mark.

Automobile Emission Standards

A group of new directives has been adopted for private car emissions.

The directive on small car emissions calls for mandatory norms from 1992 onwards. The new norms are comparable to North American standards (CO: 20g test; HC and NOx: 5g test). On the basis of current technology these norms can only be met by three-way catalytic converters. The Commission hopes that by 1992 advances in lean burn technology will be sufficient to meet the new standards.

Voluntary standards for medium-size and large cars are also expected to be tightened by 1993 and proposals to this effect were submitted to the Council at the end of 1989. They call for the introduction of standards equivalent to the strict North American norms for all medium (1400 cc to 2000 cc) and large cars (over 2000 cc) cars, starting in 1993.

The Commission is also proposing to introduce a new 7km test cycle to judge emission standards as opposed to the 4km cycle and new tougher durability tests. This means that, to meet these standards after 30,000 and 80,000 km, cars will have to be cleaner to start off with.

Adopted and Proposed EC Automobile Exhaust Emission Standards

Engine Size	Implementation Date		Emission Level Grams/Test
	New Model	New Car	
> 1.4 litres	1/7/92		CO: 2.7g HC+NOx: 0.9g
		1/1/93	CO: 3.1g HC+NOx: 1.1g
< 1.4 litres	1/7/92		CO: 19g HC+NOx: 5g
		31/12/92	CO: 22g HC+NOX: 5.8g

Source: DHS; EC 1992 Database, February 1990

Implications for Canadian Suppliers

Canada exports over \$250 million worth of automotive products to the EC. Automotive parts accounted for \$90 million of this total; passenger cars (\$60 million), trucks (\$70 million) and other vehicles (\$30 million) accounted for the rest.

The streamlining of the type approval process and the replacement of 12 national systems with one European-wide system will benefit both foreign and domestic manufacturers of automobiles, parts and assemblies.

Canadian suppliers of catalytic converters and other equipment to deal with auto emission standards could benefit from the tougher EC standards.

5.4 Machinery

Significant EC Standards Legislation Affecting the Sector

Most of the directives that are related to machinery concern essential safety standards. In addition, some machinery and equipment sectors could be affected by new EC noise pollution legislation. These include agricultural machinery, forklift trucks, lawn and riding mowers, etc.

Machinery Safety Directive

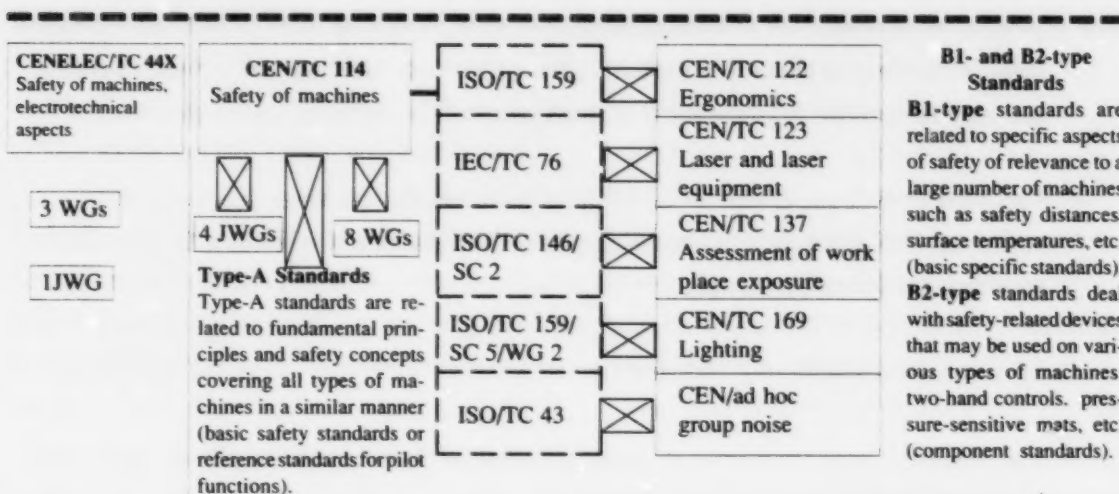
This directive applies to functioning machines, that are defined as assemblies of mechanically linked parts, at least one of which moves. The directive is very broad in scope and potentially covers several thousand types of industrial machinery.

The essential requirements are wide-ranging and include the materials used in the construction of the machinery; lighting; controls; stability; hazards related to moving parts; fire; noise; vibration; radiation; dust emissions, etc..

Additional provisions are made for agri-foodstuffs machinery, portable hand tools; and woodworking machinery.

At present, CEN has set up about 40 technical committees and working groups to produce a complex of standards at three levels in support of this directive.

CEN Standards Activities Related to Machine Safety



EXAMPLES

CEN/TC 142 Woodworking machines	CEN/TC 143 Metal-working machines	CEN/TC 144 Agricultural and forestry machines	CEN/TC 145 Rubber and plastics machines	CEN/TC 146 Packaging machines
CEN/TC 147 Cranes	CEN/TC 148 Continuous mechanical handling	CEN/TC 149 Automatic storage/retrieval equipment	CEN/TC 150 Industrial trucks	CEN/TC 151 Construction equipment and machines
CEN/TC 152 Leisure and recreational	CEN/TC 153 Food processing machines	CEN/TC 169 Lighting application technology	CEN/TC 187 Refrigeration systems	CEN/TC 186 Thermoprocessing technology
CEN/TC 188 Conveyor belting	CEN/TC 196 Mining and quarrying machinery safety	CEN/TC 197 Pump safety	CEN/TC 198 Printing and paper machinery safety	
CEN/TC 200 Tannery machines and plants	CEN/TC 201 Leather products machinery	CEN/TC 202 Machinery for hot metal processing safety	CEN/TC 213 Machines using propulsive charge-safety	CEN/TC 214 Textiles and allied machinery safety

Type-C Standards

Type-C standards comprise detailed safety requirements for a special machine or group of machines. These standards make reference--as far as possible--to relevant requirements or to the relevant safety level within a B standard that is necessary and applicable for this special machine under the special work conditions (product safety standards).

JWGs = Joint Working Groups
WGs = Working Groups

Source: US International Trade Commission 1990

As set out in the table on page 37, the first level (Type A standards) will comprise general safety codes of practice covering all types of machinery.

The second level (B1 and B2 standards) will cover specific safety devices and ergonomic aspects. For example B1 standards concern specific aspects of safety which are relevant to large numbers of machines, such as lighting and noise. B2 standards involve devices that may be used on large numbers of machines, such as controls, lasers, etc..

The third level (Type C standards) will deal with specific machines or classes of machinery by calling up appropriate standards from the first two levels and addressing requirements specific to the class.

Lawnmowers and Riding Mowers

The permitted sound power levels range between 96 dBpW to 105 dBpW according to the corresponding cutting width of the lawnmower.

Construction Machinery

The Community has placed a limitation on the noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders, and excavator loaders. The permitted sound-power level is between 106-118 dB(A)/1pW according to the net installed power in kw of the machinery.

All machines that comply will be issued with an EC type-examination certificate.

Tractors and Agricultural Machinery

A number of directives have been adopted that address certain structural and protective features on agricultural and forestry tractors.

These directives harmonize the differing national and international law that so far have made intra-EC trade a complicated matter. In particular an EC-wide type approval system has come into effect as of January 1, 1990.

Implications for Canadian Suppliers

In some product categories, such as lawn and riding mowers, the EC directives that set permissible upper limits on noise emissions means that North American producers have to lower the operating speed of their equipment or redesign the engines to make them quieter, if they are to continue to sell into the European market. Occasional exporters (especially small and medium-sized firms) could drop out of the EC market rather than meet the new requirements related to the various machinery directives.

However, the greatest effects will probably relate to the certification and testing procedures for non-EC manufacturers that will ultimately be put in place. All Canadian firms should benefit from EC-wide type approval procedures, although these benefits will be considerably diminished (especially for SMEs) if Canadian firms are required to have all testing and certification done in the EC.

Larger Canadian firms with manufacturing operations in the EC should benefit strongly from the potential to enjoy economies of scale in their European production.

5.5 Electrical and Electronic Equipment

Significant EC Standards Legislation Affecting the Sector

The two major pieces of legislation affecting standards in the electrical and electronics sectors are the information technology directive and the electromagnetic compatibility directive:

Information Technology Directive

By harmonizing standards, a major goal of the information technology directive is to provide end-to-end compatibility of information systems.

The directive applies to "the systems, equipment, components, and software required to ensure retrieval, processing and storage of information". Consequently it will affect a wide range of Canadian manufacturers of computer equipment and peripherals, ASICs, data communications products and software, and telecommunications products used for

computer communications, as well as providers of data processing services and value-added network services.

Electromagnetic Compatibility Directive

The goals of this directive are to ensure that any electromagnetic disturbance does not interfere with the operation of radio and telecommunication equipment; that all apparatus is adequately protected from electro-magnetic interference; and that electromagnetic emissions do not exceed harmful levels. The directive applies to a vast range of products, including electrical appliances, data-processing and telecommunications equipment, transportation equipment, electricity distribution equipment, and radio and television network equipment.

Implications for Canadian Suppliers

The EC market is a very significant one for Canadian producers of computers and components. Canadian exports to the EC were worth almost \$500 million in 1988.

For new entrants or small and medium-sized Canadian firms, the new European-wide standards in information technology are likely to help open European markets for their products and services. Interconnection favours such companies by offering them access to a larger customer base.

The benefits of the directive are less certain for Canadian firms with well-developed proprietary technologies, although the legislation does not require the use of European standards in special circumstances to allow for the "genuinely innovative nature of certain products".

The new European-wide electromagnetic compatibility standards are unlikely to be more stringent than existing standards in member states. Once harmonized standards have been adopted the directive could result in better market access and improved market share for Canadian suppliers.

5.6 Aerospace

Significant EC Standards Legislation Affecting the Sector

The Community has introduced legislation that sets noise reduction standards for civil subsonic jet airplanes.

Airlines with landing rights in the Community are required to comply with the most up-to-date noise standards when buying new planes. Subsonic planes with a maximum take-off mass of more than 34,000 kgs will have to meet the standards set out in the International Convention on Civil Aircraft (Chapter 3, Annex 16).

In addition the Commission has announced that it was drawing up much stronger measures to limit the operation of aircraft which do not comply with the standards of Chapter 3 of Annex 16 of the ICAO. If adopted this could effectively ground 5300 aircraft worldwide.

Implications for Canadian Suppliers

Canadian exports of aircraft and parts to the Community exceed \$180 million annually.

The EC's noise standard is not expected to affect any planes produced in Canada, unless the scope of the directive is significantly widened to include smaller aircraft. For example, the DASH 8 fifty-seat model has a maximum takeoff weight of 19,500 kg and the planned 70-seater will have a take-off weight of about 25, 000 kg.

Canadian parts and assembly suppliers to US and EC manufacturers of larger aircraft could be indirectly affected, however.

5.7 Environmental Industries

Significant EC Standards Legislation Affecting the Sector

As part of its new environmental legislation the Community is setting stricter environmental standards for air, water and noise pollution. In addition, the prevention of toxic and hazardous waste generation and the recycling of waste for re-use as energy or raw materials are important policy goals.

Water Quality Standards

Directives have been adopted setting standards for drinking water, bathing water, fresh water supporting fish life and shellfish.

The EC has also taken action against the discharge of dangerous substances by industrial plants. The Dangerous Substances directive prohibits the discharge of 129 substances on the "Black" list (mercury, cadmium, carcinogens, non-biodegradable oils, etc.) and calls for the reduction of discharges of less hazardous substances on the "Grey" list.

The Commission has drawn up a proposal for a directive banning discharges of raw untreated municipal sewage either onto land or into water.

Air Quality

There is no general system of rules protecting the atmosphere from pollution. The EC has taken a three pronged approach:

- Particular substances (such as sulphur dioxide, nitrogen dioxide, asbestos, and CFCs) are subject to general regulation.
- The fight against air pollution is also centred on specific products (auto emissions, lead in petrol).

- The third element is the regulation of certain industrial activities. For example a framework directive deals with air pollution from industrial plants. Other directives deal with the reduction of air pollution from large combustion plants and waste incineration plants.

Fight against Noise Pollution

As previously discussed in the machinery section, the fight against noise pollution at the Community level has focussed on sound levels for specific products, such as motorcycles, tractors, lawn mowers and construction machinery.

Waste Disposal

Community legislation on waste disposal includes:

- A framework directive on waste disposal which lays down the basic principles with respect to the collection, disposal, recycling and processing of wastes.
- A general directive on toxic and dangerous wastes which requires that waste containing heavy metals, pesticides, organic halogen compounds, pharmaceutical compounds, etc. must be kept separate from other matter and packaged, labelled and transported appropriately.
- Directives that apply to specific wastes (such as waste oils, waste from the titanium dioxide industry, PCB waste and spent batteries) which include the following provisions: the polluter pay principle, requirements of prior authorization of any enterprise handling such waste, the obligation to avoid dumping these substances, and the tendency to favour the recycling of waste.
- A directive on the transfrontier movement of toxic and dangerous wastes, which seeks to establish a watertight system which would ensure the uninterrupted supervision and monitoring of movements of waste entering, within and leaving the EC.
- A proposed directive has been introduced that would hold producers legally liable for environmental damage caused by the wastes that they produce. It will

place a strict, no-fault liability on the producers of waste. By making the producer bear the costs, the proposal hopes to make the development of clean technologies and other ways of minimizing waste more attractive.

Implications for Canadian Suppliers

With the significant exceptions of auto emission standards, and noise pollution standards (addressed in the auto and aerospace and machinery sections above) these developments do not constitute technical barriers to trade. On the contrary, they could have the effect of opening up new market opportunities for competitive Canadian suppliers.

The West European market for pollution control equipment - everything from advanced waste disposal technology to catalytic converters - is already worth \$40 billion annually.

It is estimated that the cost of reducing sulphur emissions from power stations and factories will soon reach \$5 billion a year.

The powerful EC chemical industry (Germany has the second largest chemical industry in the world after the US) will be looking for expertise and technology to assist it in addressing environmental problems related to toxic waste disposal, gaseous and water emissions, and genetic engineering.

The EC's environmental legislation should open up significant new markets for competitive Canadian suppliers of environmental monitoring and control equipment, process control technologies, and consulting and engineering services.

However, Canadian suppliers will be faced with well-established and technologically sophisticated European competitors. It is estimated that more than a million people in the European Community are employed in the pollution control industry and its related services.

5.8 Chemicals and Pharmaceuticals

Significant EC Standards Legislation Affecting the Sector

Chemical products are affected by EC directives on marketing and composition of fertilizers and detergents; construction products; good laboratory practice; labelling of cosmetic products; and the marketing, labelling and packaging of dangerous substances.

Pharmaceuticals will be subject to common approval, clinical evaluation and testing requirements under EC directives for registration in all member states. The EC has adopted directives on procedures for market authorizations of proprietary medicinal products and has also introduced protocols for testing such products. These directives are intended to shorten the current 4-6 month period for technical evaluations of applications for product licencing.

Implications for Canadian Suppliers

Canadian exports of chemical products (including plastics and pharmaceuticals) to the EC totalled \$650 million in 1988. The EC is Canada's second largest single market after the US, although the countries of the Pacific Rim collectively represent a larger and more dynamic market. The three major Canadian chemical exports to the EC are uranium, styrene and phosphorous.

Canadian commodity chemical exports to the EC are unlikely to be affected adversely by changing European product standards, since, given the international competitiveness of EC chemical producers and their export interests, they are likely to encourage the development of internationally-oriented product standards.

The EC's proposed directive on civil liability for chemical and other wastes goes beyond the traditional approach that the producer is responsible for wastes until they are handled over to a transporter. The directive would extend the producer's liability to the transport and disposal phase and could have important implications for certain Canadian exporters.

EC directives on pharmaceuticals could facilitate access for Canadian products through the adoption of common procedures.

Exports of medical applications of biotechnology products depend heavily on obtaining product licencing approvals from national authorities. If, as intended, the 1992 program results in transparent licencing procedures, a number of Canadian firms that have been discouraged from entry into certain member states in the past should find it worthwhile to renew their attempts at market entry.

5.9 Processed Foods

Significant EC Standards Legislation Affecting the Sector

Technical barriers have long fragmented the Community's processed food market.

The EC has identified five principal types of barriers that have kept national markets separate. These are differing national labelling and packaging rules; bans on specific ingredients in certain countries (eg aspartame in non-alcoholic beverages in France); content and description rules (eg pasta purity laws in Italy, beer purity laws in Germany); tax discrimination; and specific import restrictions.

The Community's 1992 strategy to create an internal market for processed foods is to harmonize national regulations and standards to protect public health, provide consumer protection, ensure fair trading and provide for necessary public controls. In areas where there is no harmonization, member states must mutually recognize each others standards and regulations so that a product that is acceptable in one market can be sold throughout the Community.

The processed food directives can be separated into three categories:

- Seven framework directives which lay down the philosophy and controls for a particular area. These deal with additives, contact materials, labelling, food for particular nutritional uses, official inspection of foodstuffs, irradiation of foods, and labelling for nutritional purposes.
- Specific directives which discuss the application of the framework directives to particular categories of food.
- Product directives which address specific foods.

Implications for Canadian Suppliers

The direct benefit of removing technical barriers to trade should be to reduce costs for food processors by giving them the ability to use less expensive ingredients, the reduction in packaging and labelling costs, and the elimination of bureaucratic border controls. New firms should find it possible to enter formerly closed segments of the market. Ultimately intra-Community trade in foods should grow and consumer choices should increase.

Canadian exporters to the Community should generally benefit from the cost reductions and from the opening of the EC market that will result from the removal of technical barriers to trade. However, certain developments could make exporting more difficult for Canadian firms in some food sectors. For example:

- The Commission has set up a Food Advisory Committee to help it develop new food standards. Since Canadian exporters have no input into this process, food standards could be developed in the EC that are inimical to Canadian export interests.
- The use of positive lists of acceptable ingredients in a number of the food directives could also pose problems for some exporters. For example, both the EC's directive on emulsifiers, stabilizers, thickeners and gelling agents and the directive on infant formula do not include substances that are permitted in North America. Since the process for obtaining approval for the inclusion of a new ingredient on a positive list can take years, exporters faced with this problem would normally have no choice but to modify their formulas.
- The directive on quick-frozen foods could also pose problems. The definition of quick-frozen foods and the temperature requirements imposed by the directive vary from the UN guidelines, set out in the Codex Alimentarius, followed by North American producers. This raises the risk of Canadian frozen foods being denied access to the EC market.

6. IMPLICATIONS FOR CANADA

6.1 Overall Assessment

The EC's 1992 standards agenda will result in both benefits and risks for Canadian suppliers in Europe. However, on balance, the EC program to harmonize standards setting, testing and certification procedures is good news for Canadian firms wishing to do business in Europe.

Many major Canadian export sectors to the EC should be net beneficiaries from the adoption of single European wide standards and a simpler and more flexible testing and certification process.

Many aspects of the 1992 standards program should be particularly beneficial to small and medium-sized Canadian firms (SMEs). Uniform standards will let SMEs take advantage of potential economies of scale. Once their products are certified, SMEs should be able to sell them throughout the Community without further testing. Canadian firms will not have to make expensive modifications to sell their products in twelve different countries.

6.2 Benefits

The new standards setting, testing and certification system in the EC should generally reduce administrative burdens, lower costs and generate new opportunities for Canadian producers. Specific benefits should derive from the following developments:

Some Standards should have a Market-Creating Effect

In the past, the lack of common standards between member states has made it impossible to develop and sell certain products on a European-wide basis (for example as in the case of mobile telephones). The adoption of European standards for digital cellular radio, therefore will create a market opportunity that formerly did not exist.

Benefits from a More Coherent and Transparent System

Canadian firms (exporters and firms manufacturing in the EC) will, in general, face a more coherent, more open, more transparent and more organized marketplace in the EC.

The Commission has drawn up the procedures for testing and certification so that they could be applicable at the same time to voluntary standards as well as to regulated standards.

Benefits of One Set of European Standards

Canadian exporters and manufacturers that had to produce to twelve different sets of industrial standards or technical regulations to access the EC market of 325 million consumers will now be able to produce to one set of standards and go through one set of procedures to get the product tested and certified.

The benefits of a single set of standards are not confined to the twelve member states of the European community. The 1992 standards program also involves the six EFTA countries. In addition, it is highly likely that, as economic liberalization proceeds, Eastern European countries, too, will adopt Western European standards. The benefits of the EC initiative could extend to include a European market of over 500 million people.

Potential European Standards Area

EC COUNTRIES

Spain
Portugal
Netherlands
Belgium
Italy
Germany
France
Ireland
Denmark
Greece
U.K.
Luxembourg

EFTA COUNTRIES

Sweden
Norway
Iceland
Switzerland
Austria
Finland

EAST EUROPE

Poland
Hungary
Romania
Czechoslovakia
Yugoslavia
Albania
Bulgaria

Source: US Department of Commerce, 1990

Benefits of Improved Access to Government Procurement Market

The development of European standards is an important component in opening up the government procurement market in the EC. The revised Community directives on public supplies and works, and the directive covering procurement by entities in the telecommunications, transportation, energy and water supply sectors, all require purchasing entities to specify European standards wherever they exist (subject to some limited exceptions).

Benefits from the Flexible Certification Procedures

Since a manufacturer has a choice of certifying a product either against the essential requirements set out in a directive or against the relevant European standard, this reduces the need for a Canadian exporter to produce goods for the Community market to unnecessarily detailed specifications.

Benefits from the Principle of Mutual Recognition

Where no European standard exists, Canadian firms will also benefit from the principle of mutual recognition, namely that a product accepted for sale in one member state must be free to circulate to all member states.

Benefits from the Principle of Non-Discrimination

The principle of non-discrimination means that products originating in Canada must be granted access to certification systems on an equal footing to products originating in the Community, whether the system is voluntary or mandatory. Canadian products can only be refused for the same reasons as products originating in the EC, namely non-conformance and lack of safety.

6.2 Sectoral Benefits

As demonstrated in the previous section, both Canadian exporters and Canadian firms with manufacturing investments in the EC should benefit from the EC's initiative to harmonize standards setting, testing and certification in the EC. The following summary table indicates that all major Canadian export sectors to the EC should benefit from EC standards developments, although the benefit-risk ratio varies significantly between sectors.

EC 1992 Standards Developments Impacts on Selected Major Canadian Export Sectors to the EC

Sector	Magnitude of Positive Impact	Magnitude of Negative Impact
Telecom Equipment	Strong	Small
Telecom Services	Medium	Small
Forest Products	Strong	Medium
Autos and Parts	Medium	Small
Machinery	Medium	Small
Environmental Equipment	Strong	Small
Electrical/Electronic	Medium	Medium
Aerospace	Small	Small
Processed Foods	Medium	Medium

Source: See Section 5 of main report

6.3 Concerns

Nevertheless from the Canadian perspective there are some concerns with both the standards-setting process and the EC's proposed arrangements for testing and certification.

The concerns of Canadian industry with the EC's standards setting process revolve around the following issues:

Lack of Transparency

In view of the ambitious scale of the reform underway in the EC, and the complexity and fluidity of the process, many small and medium-sized Canadian firms are having difficulties getting timely information on standards-related developments in the Community.

Of particular concern to Canadian exporters is the lack of transparency with respect to the European standards setting bodies, especially CEN, CENELEC and ETSI.

Effective Access to the Standards Setting Process

Even when information is available, it may be too late to influence the draft standards so that they reflect Canadian interests.

Canadian exporters do not have formal channels for direct influence in the crucial pre-proposal stage of the EC directives.

In response to concerns from the US and Canada, CEN and CENELEC have recently clarified procedures for third country involvement in the standards setting process. CEN and CENELEC now submit draft standards to standards organizations in both Canada (the Standards Council of Canada - SCC) and the US (ANSI), as well as to the ISO, for comment. In addition, non-EC firms could be invited by the chair of the technical committee to submit their positions. ETSI will soon establish similar arrangements with the SCC.

There is little evidence yet on the extent to which European standards setting will reflect inputs from non- EC interests.

It is likely that Canadian manufacturers will continue to be confronted with the need to modify their product designs and testing procedures to meet new European standards. Sometimes the changes will have to be made with very short lead times if the Canadian exporter is not to lose market share.

Incompatible or More Stringent EC Requirements

Where EC standards are different from or incompatible with Canadian standards or testing requirements, the effect of these differences will be to raise costs for Canadian exporters seeking to pursue the EC market; in some situations the effect could be to exclude Canadian products from the EC market.

There is also some risk that harmonized new European standards could include more stringent health and safety requirements than may be necessary, which could act as barriers to trade.

Undermining of International Standards

In addition, while CEN and CENELEC have undertaken to use international standards where possible, there is concern that the heavy workload for 1992 could detract from their participation in ISO (the International Standards Organization) and IEC (the International Electrotechnical Commission), with the result that European standards will emerge in preference to international standards.

Procedures for mutual recognition of certification and testing of third country suppliers are a critical element of the EC's 1992 standards agenda. If Canadian firms are required to submit their products for testing and certification to European testing facilities, this could add considerably to the cost and difficulty of marketing goods to the EC.

With respect to the new European testing and certification procedures, three critical issues have emerged so far:

Arrangements for Third Party Testing

First, when third party testing is required, the EC has indicated that it will only accept the results from an EC-recognized testing facility, unless a bilateral agreement has been negotiated with a third country.

The Type-Approval Process

Second, the type-approval system has some drawbacks when compared with a self-certification system.

In a type-approval system, if an innovation is not covered by a regulation the product may not be type approved until an existing regulation is amended or a new one developed.

One of the most important consequences is that it can constrain the ability to commercialize high technology products.

The adoption of the type-approval process on an EC-wide basis may, therefore, act to inhibit certain high technology exports from Canada to the EC.

Importance of Quality Assurance

Third, the EC modular approach to certification places a strong emphasis on quality assurance programs. There have already been examples where Canadian exporters have been required by their EC customers to introduce QA programs.

It is inevitable that, over the next few years, more and more Canadian exporters to the EC will have to put in place QA programs.

7. RECOMMENDATIONS FOR CANADIAN BUSINESS

This section identifies the major strategic actions that should be considered by the Canadian business sector.

Ignoring EC standards-related developments could be a costly mistake for Canadian business. It could result in forgone opportunities or diminished competitiveness in Europe. Therefore, if Canadian suppliers are to reap the benefits of the EC's 1992 standards initiative, they will have to plan their business strategies now, bearing in mind that the process of technical harmonization is proceeding briskly.

The action steps that should be considered by all firms with an interest in the European market in order to assess the opportunities and the threats presented by new EC standards are set out in the following sections:

7.1 Identify Which Directives Could Affect Your Business

EC directives set out the legislative framework within which particular standards are subsequently developed.

The directive will normally include the following information - the types of products or sectors it covers; the essential safety, health or environmental requirements that must be met by any product offered for sale in the Community; the options that are open to the manufacturer to demonstrate that his product conforms to the requirements of the legislation; any relevant standards that must be met; and when the directive comes into effect.

Section 5 of this Report has identified many of the major directives that could affect broad Canadian export sectors. In addition Appendix D lists the regulated product groups that are covered by new approach and other EC directives.

For further information on specific directives, excellent sources of information in Canada include the Department of External Affairs in Ottawa and the Standards Council of Canada (SCC).

Canadian firms with US or European affiliates could also seek information from the Department of Commerce in Washington DC, from the Department of Trade and Industry or the British Standards Institute in the UK, or from standards bodies and government agencies in other member states.

Relevant contact points and phone numbers are provided in Appendix A.

7.2 Identify Which Standards Could Affect Your Business

Specific European standards are written by the European standards bodies (CEN, CENELEC, and ETSI).

The Standards Council of Canada (SCC) has been funded by External Affairs to provide draft EC standards to all interested parties and to handle the comments received. At present this applies in the case of draft CEN and CENELEC standards, and similar arrangements are anticipated in the next few months with respect to ETSI standards. The SCC can also provide information on final standards adopted by CEN, CENELEC and ETSI.

Since July 1, 1990, the SCC has been distributing a monthly newsletter with summaries of the new draft European standards and it also offers an on-line service. SCC provides information on French, British and German standards and technical regulations.

7.3 Reassess Your Marketing Strategy in Europe

The creation of a new European-wide regime for standards and certification may necessitate a reassessment of a firm's marketing strategy. For example:

- The principle of mutual recognition may have implications for which member state is chosen as the point of entry into the EC market. The mutual recognition principle means that a product accepted for sale in one member state must be free to circulate to all member states. Therefore, after 1992, if a Canadian product meets Spanish standards or technical requirements it will have to be admitted into the German market, even if it may not conform to German standards.

This will not be an issue if a European standard exists. However, it may be an important consideration if progress remains slow with respect to developing new European standards or creating a system of mutual acceptance of testing and certification between member states.

- Customer preferences may mean that the CE mark is not sufficient to meet with automatic customer acceptance. Purchasers may also look for national marks or quality certificates as demonstrations of product quality or conformity.
- If a product needs third party testing and certification it will be necessary to establish which notified bodies, either inside or outside the Community, are accredited to perform such tests.
- Product redesign may be necessary to meet European standards.

In the event that a Canadian firm needs to modify a product to meet new EC standards, assistance may be available through the federal government's PEMD program or through Ontario's Trade Expansion Fund.

7.4 Take Measures to Promote Your Interests in Brussels

Companies in the various member states in the EC are being urged by their national governments to get actively involved in the standards setting process in CEN, CENELEC and ETSI to ensure their interests are reflected.

This will be more difficult for Canadian exporters than for Canadian firms with a manufacturing or business presence in the EC. Nevertheless there are direct and indirect options available to Canadian exporting firms:

- An exporter might be able to work through a strategic partner in the EC.
- An exporter might be able to work through a trade association which may have links with a European industry association that is prepared to support the Canadian position.

- European consumers and purchasers of Canadian products may be interested in representing the Canadian viewpoint.
- An exporter could seek the assistance of the Canadian government to influence developments in the EC.

7.5 Push for Reciprocal Testing Arrangements

There is general agreement that Canadian suppliers face a greater risk of being shut out of the EC market through testing and certification procedures than from meeting the cost or inconvenience of meeting different European standards.

Therefore Canadian firms should push for testing arrangements that will enable them to have their products, processes or companies certified in Canada for the EC market. Canadian business should act on two fronts:

- With respect to regulated European standards, it will be essential for the Canadian government to negotiate a reciprocal government to government deal with the Community. The likelihood of such a deal will increase if the Canadian government is confident that it has the backing of the business community and if Canada is prepared to allow reciprocal testing and certification to take place in EC member states.
- With respect to voluntary standards, the EC Commission has made it clear that these are to be negotiated by the private sector. The CSA already has negotiated agreements with BSI in the UK and KEMA in the Netherlands which provide for reciprocal recognition of evaluations for testing, inspection, certification and assessment of quality systems.

The CSA is unlikely to enter into further bilateral arrangements with EC standards and testing organizations unless it has the strong backing of interested Canadian companies who might benefit from such arrangements.

7.6 Consider Adoption of a Quality Assurance System

One of the ways in which products can be certified to be in conformance with European standards is for the supplier to adopt a quality assurance system. There are three options: a QA system for the relevant products; a QA system for the relevant production; or a total QA system for the enterprise.

In addition, European purchasers are increasingly looking to the adoption of a QA system as a prerequisite in their suppliers - especially their offshore suppliers.

A number of prominent Canadian exporters to the EC have already initiated programs to have their plants certified against EN 29000 standards. Certification is done in Canada by the QMI, which is a division of the Canadian Standards Association.

Clearly, Canadian firms with a long term strategy to the European market should give active consideration to adopting a QA system.

APPENDIX A

LIST OF INFORMATION SOURCES

1. Standards Council of Canada
Information Division
350 Sparks Street
Suite 1200
Ottawa K1P 6N7

Tel: (613) 238-3222 or 1-800-267-8220
Fax: (613) 995-4564
2. Department of External Affairs
Industrial Trade Policy Division
125 Sussex Drive
Ottawa K1A 0G2

Tel: (613) 996-8190
Fax: (613) 952-3904
3. Department of External Affairs
EC Trade and Economic Relations
Division
125 Sussex Drive
Ottawa K1A 0G2

Tel: (613) 996-2727
Fax: (613) 995-1277
4. Delegation of the European Communities
350 Sparks Street
Suite 1110
Ottawa K1R 7S8

Tel: (613) 238-5191
5. US Department of Commerce
Office of European Community Affairs
International Trade Administration
Washington DC 20230

Tel: (202) 377-5276
6. US Department of Commerce
National Institute of Standards and
Technology
National Centre for Standards and
Certification Information
Gaithersburg, Maryland 20899

Tel: (301) 975-4040
7. UK Department of Trade and Industry
123 Victoria Street
London SW1E 6RB
England

Tel: 071-215 6272
8. British Standards Institute
2 Park Street
London W1A 2BS
England

Tel: 071- 629 9000
9. Canadian Standards Association
178 Rexdale Boulevard
Rexdale, Ontario, M9W 1R3

Tel: (416) 747-4011
Fax: (416) 747-2675
10. Quality Management Institute
1420 Mississauga Executive Centre
4 Robert Speck Parkway
Mississauga, Ontario, L4Z 1S1

Tel: (416) 272-3920
Fax: (416) 272-3942

APPENDIX B

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APPENDIX C

INDIVIDUALS INTERVIEWED

Standards Bodies

Larry ROGERS, President, QMI, Mississauga.

John KEAN, President, CSA, Rexdale.

Diane THOMPSON, Manager, Information Division, Standards Council of Canada, Ottawa.

Government Officials

Keith AIRD, Deputy Director, Industrial Trade Policy Division, Department of External Affairs, Ottawa.

Mitch VLAD, European Trade Policy Division, Department of External Affairs, Ottawa.

Doug DOES, Senior Director, Alberta Economic Development and Trade, Edmonton.

Richard LYALL, Policy Analyst, Ontario Ministry of Industry Trade and Technology, Toronto.

Jonathon PHILLIPS, Head of International Telecommunications Branch, Department of Trade and Industry, London, UK.

Industry Representatives

Judith SCOTT, Vice President UK Sales, Gandalf Digital Communications Ltd, Ottawa.

Graham NASH, President, Mining Association of Canada, Ottawa.

Don WIESMA, Canadian Manufacturers Association, Toronto.

Frank HLOHOVSKAY, MEMAC, Ottawa

Terry MCDONALD, Boeing - De Havilland, Downsview

APPENDIX D

EC DIRECTIVES THAT REGULATE VARIOUS PRODUCT GROUPS

New Approach Directives That Have Been Agreed:

- Simple Pressure Vessels
- Toy Safety
- Construction Products
- Electro-magnetic Compatibility
- Machine Safety
- Personal Protective Equipment
- Non-automatic Weighing Equipment
- Gas Appliances
- Active Implantable Electromedical Equipment

New Approach Directives Under Discussion:

- Active Medical Devices (Not Implanted)
- Non-active Medical Devices
- Mobile Machinery and Lifting Equipment

Sectoral Directives:

- Automobiles, Trucks, Motorcycles
- Agricultural and Forestry Tractors
- Cosmetics
- Pharmaceuticals
- Construction Products
- Medical Specialties
- Foods and Food Ingredients

- Animal Feedstuffs
- Detergents
- Fertilizers
- Solvents
- Chemicals

Source: DTI; Single Market Factsheet 4, London, February 1990 ANSI; ANSI Global Standardization News, Volume 2, Brussels, 1990

APPENDIX E

ELEMENTS OF A "NEW APPROACH" DIRECTIVE

Scope:

This describes the range of products covered by the directive.

Essential Requirements:

This provides a statement of the "essential requirements" relating to health, safety or the environment that the products covered by the directive must satisfy before they may be sold in the Community.

This statement is written in general terms.

Generally, all products sold anywhere in the Community must satisfy the "essential requirements", not just products intended to be traded across national boundaries.

Methods of Satisfying the Essential requirements:

The usual method of satisfying the "essential requirements" will be by manufacture in conformity with specified European standards.

However, the use of standards will be voluntary, and manufacturers will have the option of demonstrating conformity with the "essential requirements" themselves.

Conformity Options:

The envisaged forms of conformity with the "essential requirement" are:

- A declaration by the manufacturer (backed up by his own, or independent test results);
- The certificate of an independent body;
- The test results of an independent body; or
- Some variant of these methods.

Transitional Arrangements:

If a European standard does not yet exist, national standards approved for that purpose by the European Commission may be used instead. Otherwise the EC type-examination route has to be followed.

Free Circulation

A product that has been properly attested as conforming to the essential requirements and has been EC-marked is presumed to be entitled to be sold freely throughout the Community.

Safeguard Procedure

A member state may prohibit or withdraw a product from the market on the grounds that they do not satisfy the essential requirements.

However, the member state must inform the Commission of the reasons for its action. If the Commission finds no basis for the prohibition, the member state will have to rescind its prohibition or the action may be brought before the European Court of Justice.

Other Directives:

Since New Approach directives relate essentially to a class of risks, more than one directive may apply to any product.

Therefore, products that comply with a given directive may also have to comply with other relevant legislation.

Implementation:

The directive will indicate when the legislation will come into force.

Standards:

The directive will identify any relevant standards that apply.

SOURCE: DTI; The New Approach to Technical Harmonization and Standards, 1989.

APPENDIX F

MODULES FOR CONFORMITY ASSESSMENT PROCEDURES

Module A: Internal Production Control

The manufacturer ensures and declares that the product concerned satisfies the requirements of the directive.

Module B: EC Type Examination

A notified body ascertains conformity with essential requirements, either on the basis of technical documentation submitted by the manufacturer or by carrying out its own tests.

The notified body will then issue the manufacturer an EC type-examination certificate.

Module C: Conformity to Type

The manufacturer declares that the products concerned are in conformity with the type as described in the EC-type examination certificate.

Module C is designed to be used in combination with module B (Type Examination).

Module D: Production Quality Assurance

If the manufacturer operates an approved quality system for production, final product inspection and testing, he would declare that the products concerned satisfy the requirements of the directive.

Assessment and audit of the quality system would be made by an appropriate notified body.

Each product would carry the identification symbol of the notified body responsible for the surveillance.

Module D will normally be used in combination with module B (Type Examination), except in the case of products of very simple design and construction when it might be used on its own.

Module E: Product Quality Assurance

If the manufacturer operated an approved quality system for final product inspection and testing, he would declare that the products concerned satisfied the requirements of the directive that apply to them.

A notified body would assess the quality system and carry out periodic audits.

Each product would carry the identification symbol of the notified body responsible for the surveillance.

Module E will normally be used in combination with module B (Type Examination), except in the case of products of very simple design and construction when it might be used on its own.

Module F: Product Verification

The manufacturer arranges for a notified body to carry out appropriate examinations and tests to verify the conformity of the product to the approved type or to the essential requirements. This may be done either by examining and testing every product or by statistical verification.

The notified body would issue a certificate of conformity.

Module F will normally be used in combination with module B (Type Examination), except in the case of products of very simple design and construction when it might be used on its own.

Module G: Unit Verification

The manufacturer would have to submit the product to a notified body, which would have to examine the individual product and carry out the appropriate tests to ensure conformity with the directive.

The notified body would issue a certificate of conformity.

Module H: Full Quality Assurance

If a manufacturer operates an approved quality system for design, manufacture and final product inspection and testing, he would declare that the products concerned satisfied the requirements of the directive that apply to them.

A notified body would assess the quality system and carry out periodic audits.

Each product would carry the identification symbol of the notified body responsible for the surveillance.

Source: European Council; Draft Council Decision 10828/89, Annex 1.

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